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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,173	01/08/2004	John L. Sommer	P-10537.03	8459

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EXAMINER	
BOCKELMAN, MARK	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/754,173	SOMMER ET AL.	
	Examiner	Art Unit	
	Mark W. Bockelman	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 9-24* is/are rejected.

7)☒ Claim(s) *4-8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1-8-2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 16-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant fails to disclose how each of the means recited in claims 16-18 provide an adjusting means. While each of these means monitors the fluid delivery tip when implanted, they do not adjust the position.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 9-11, 19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lesh et al. USPN 6,716,196.

Lesh et al. show in figures 10a and 10b, a lead member in the form of a braided catheter which may have mapping electrodes thereon (see elements 108 (fig 8). The lead member also has a fixing portion formed by extendable/ retractable anchoring needles 144. A fluid delivery member in the form of a helical coil threadably engages a seal member in the lumen and also has threads at the proximal end for engaging threads in the wall of the lumen to permit the fluid delivery device to pass through the lumen and extend out the distal end.. The port 68 would form a stop member as well as an indicator by it positioning from the distal end of the catheter inlet. The curved coil would be directed away from the fixing member when screwing it in to tissue. In regard to claim 19, applicant's embodiment wherein the monitoring means is an impedance monitoring device which requires the use of electrodes to measure an impedance. Thus the bolus of injected fluid alone, as claimed in 19, has not accompanying steps to make use of the bolus. To the extent that applicant monitors the distal tip by merely injecting a bolus of conductive fluid, the Lesh also monitors the fluid delivery device by injecting a bolus of conductive ablation fluid (column 2 lines 40-41). While Lesh et al does not state that the fluid delivery device is adapted to be inserted to the proximal port, it would seem apparent that during it's assembly such would be the case

Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lesh et al. USPN 6,716,196. Applicant differs from Lesh et al in reciting the use of shape memory alloys for making fluid delivery device. Such materials would have been an obvious choice of materials well known to the art as demonstrated by Lesh et al, who makes the tubular electrode out of hypotube or Nitinol.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lesh et al. USPN 6,716,196. Applicant differs from Lesh et al in reciting a lubricious coating on the fluid delivery device, which would have been an obvious modification to ease the delivery device through the distal seal.

Claims 1, 9-10, 14-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis et al USPN 6,416,490 in view of Edwards et al. USPN 5,935,123. Ellis et al, in figures 4 and 5, shows a lead body 21 and a fluid delivery device in the form of a needle electrode 36 in the lumen of the lead body. The needle may deliver contrast fluid and or ablation fluid. Fluoroscopy may be used to monitor the degree of ablation by the injectable contrast media placed in the tissue by Ellis. Applicant differs in reciting the needle is insertable through a proximal port and having means for adjusting the penetration depth. It is unclear if the Ellis et al needle is insertable or not, however, it would have been obvious to make it so since such an arrangement is standard as demonstrated by Edwards et al. and which has a handle member for adjusting the needle depth by pushing or pulling on the handle. The handle also serves as a lockable cap. To have include such features to adjust the depth of substance delivery and to stablize the structure would have been obvious. The Ellis power delivery is based upon the tissue impedance and to have provide an impedance measuring unit to test the conductivity of the tissue with conductive fluid injected therein would have been obvious. To have provided a pressure measuring device on the injector of the attached to the needle to assure tissue penetration depth and proper injection pressure avoid

damaging healthy tissue would have been obvious. Such "feel" techniques are known in the art.

Claims 1-3, 9-10, 14-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis et al USPN 6,416,490 in view of Lesh et al. USPN 6,716,196. As noted above Ellis teaches and provides motivation for most of the limitations in the claims above with the exception of the means for adjusting having threads. Lesh et al shows an arrangement using threads for adjusting the depth of an implantable needle electrode using such threading. To have provided the Ellis et al needle and lumen with cooperating threading to adjust the needle depth would have been obvious.

Allowable Subject Matter

Claims 4-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant provide for a lead clamping portion as well as a fluid device clamping portion. The prior art does not teach a portion that clamps a lead and attached to a portion that clamps the fluid delivery device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W. Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 10:00 to 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272 -6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWB

September 27, 2006

MARK BOCKELMAN
PRIMARY EXAMINER